CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

2231 '99 JUN 10 P4:31

June 8, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: International Standard-Setting Activities; Codex Alimentarius Commission; Committee on Nutrition and Foods for Special Dietary Use; Background Paper to Identify Perspectives and Issues Pertaining to International Guidelines on Vitamin and Mineral Supplements [Docket No. 99N-0391].

The Center for Science in the Public Interest (CSPI)[1] submits these comments to address issues that should be included in the briefing paper that the U.S. Government is drafting for the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). Our comments focus on two of the topics listed in the notice:

Topic 4 Setting maximum levels for vitamins and minerals in supplement form:

See Attachment 1: Dec. 5, 1997 comments of CSPI at 2-3.
See Attachment 2: CSPI comments submitted to Codex Committee on Nutrition and Foods for Special Dietary Uses September 1998.

Topic 7 Labeling, Warning Statements and Claims:

See Attachment 1: at 3-4.
Attachment 2.

Respectfully submitted,

Ilene R Heller

Ilene Ringel Heller
Senior Staff Attorney

99N-0391

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[1] CSPI Is a non-profit consumer organization supported by more than 1,000,000 members. CSPI has worked since 1971 to improve national health policies in the areas of food safety and nutrition. We have a longstanding interest in ensuring that product labeling provides consumers with truthful, scientifically valid, and non-misleading health information.

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CSPI Center for Science in the Public Interest
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December 5, 1997

Dr. Robert Moore
Food and Drug Administration
Office of Special Nutritionals
HFS-456
200 C Street, S.W.
Washington, D.C. 20204

Re: Request for comments on draft Codex guidelines for vitamin and mineral supplements CL1997/12-NFSDU

The Center for Science in the Public Interest (CSPI)[1] submits these comments regarding the United States' position on the Codex Alimentarius Commission's proposed draft guidelines for vitamin and mineral supplements. We are concerned that the decision to return the guidelines to Step 3 for further comment and consideration will delay the issuance of guidelines to ensure the safe use of vitamin and mineral supplements. We believe that the adoption of these guidelines is essential to ensure that consumers do not consume excessive levels of substances that could lead to tragic adverse health consequences.

I. Background

As the Food and Drug Administration (FDA) is well aware, the regulation of vitamins and minerals in this country has had a very controversial history. Under current law, the FDA cannot set maximum levels of potency for vitamins and minerals, or consider vitamins and minerals to be drugs, solely because their potency is greater than that which FDA determines to be nutritionally

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Attachment 1

rational.[2] Moreover, since 1994, Congress has placed the burden of proof on the FDA to establish that a dietary supplement is unsafe before removing it from the marketplace.[3]

Despite the fact that the U.S. Congress has made it exceedingly difficult for the FDA to regulate the sale of vitamins and minerals, the FDA can still prohibit the sale of any vitamin and mineral supplement in dosages that pose "a significant or unreasonable risk." The FDA should, thus, support efforts by Codex to ensure that vitamins and minerals are marketed in safe dosages.

II. Discussion

It is clear that some vitamin and mineral supplements can pose risks at excessive doses. For example, excessive consumption of:

- **Vitamin A** has been linked to miscarriages and birth defects, including malformations of the cranium, face, heart, thymus, and central nervous system. Large doses of Vitamin A have also been associated with headache, vomiting, double-vision, baldness, bone abnormalities and liver damage.[4]
- **Vitamin D** can lead to calcium deposits in soft tissues and result in irreversible renal and cardiovascular damage. Young children are most at risk.[5]
- **Vitamin B6** can cause the failure of muscular coordination and functional disturbances and/or pathological changes in the sensory system.[6]

In addition, even small doses of some vitamins and minerals may produce toxic effects.

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[2] Federal Food, Drug and Cosmetic Act (FDCA) § 411(a), 21 U.S.C. § 350(a).

[3] FDCA § 402(f), 21 U.S.C. § 342(f) (codifying Dietary Supplement Health and Education Act).

[4] National Research Council, *Recommended Dietary Allowances* (10th ed. 1989) at 87.

[5] *Id.* at 96-97.

[6] *Id.* at 146.

For example, adverse reactions from selenium have been reported at daily dosages as low as 1 mg, which have been linked to fingernail changes and hair loss. At dosages as high as 27.3 mg per tablet, symptoms include: nausea, abdominal pain, nail and hair changes, functional disturbances and/or pathological changes in the peripheral nervous system, fatigue and irritability.[7]

Therefore, it is essential that the FDA support international efforts to ensure that supplements are available only in safe doses. Neither section 411 of the FDCA nor DSHEA prohibit the FDA from taking regulatory action against a dietary supplement that "presents a significant or unreasonable risk of illness or injury" or poses "an imminent hazard to public health or safety."[8] The portions of the Codex proposal that we urge the FDA to support do not conflict with the agency's Congressional mandates. Therefore, the FDA should urge Codex to approve the following sections of the Proposed Draft Guidelines with the modifications we suggest.

3.2.1. Supplements may contain vitamins and minerals up to a level that is considered safe on the basis of risk assessment considerations, as determined by appropriate risk assessment methodology, taking into account all sources of nutrients in the diet.

3.2.2. The maximum level of each nutrient contained in a vitamin and mineral supplement should not exceed the estimated safe intake per daily dose.

In addition, CSPI supports the labeling provisions contained in section 8.5 of the draft guidelines. In particular, we urge the adoption of a requirement for warning statements "if the product contains a significant amount of a nutrient with respect to the toxicity level." Such a provision is consistent with the warning label provisions in the Dietary Supplement Health and

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[7] *Id.* at 221.

[8] FDCA § 402(f)(l)(A) and (C), 21 U.S.C. § 342(f)(1)(A) and (C).

Education Act (DSHEA).[9]

III. Conclusion

For the foregoing reasons, we urge the FDA to support the proposed Codex provisions on safe vitamin and mineral supplement dosages.

Respectfully submitted,

Bruce Silverglade
Director of Legal Affairs

Ilene Ringel Heller
Senior Staff Attorney

[9] FDCA § 403(s), 21 U.S.C. § 343(s).

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

Codex Committee on Nutrition and Foods for Special Dietary Uses
Twenty-First Session, Berlin, 21-25 September 1998

Agenda Item 5
PROPOSED DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS

Comments of the Center for Science in the Public Interest
(At Step 4 of the Procedure)

We believe that the adoption of these guidelines is essential to protect consumer health and we urge the Committee to advance them. In light of the growing popularity of dietary supplements, it is especially important that guidelines for their safe and appropriate use be developed and timely submitted to the Commission for consideration.

We wish to provide the following specific comments:

Section 3.2.1 -- We support the alternative version of this section, e.g. "Supplements may contain vitamins and minerals up to a level that is considered safe on the basis of risk assessment considerations, as determined by appropriate risk assessment methodology, taking into account all sources of nutrients in the diet."

Section 3.2.3 -- We support this section.

Section 7. 3 -- We support this section. Many tragic incidents have occurred due to certain vitamin and mineral supplements that were not distributed in child-resistant packaging.

Section 8.5 -- We support this section with the bracketed language, e.g. "The label must contain a warning statement if the product contains a significant amount of a nutrient with respect to the toxicity level." For purposes of clarity, however, this section might be reworded as follows: "The label must contain a warning statement if the product contains a nutrient that may be toxic at certain levels."

Attachment 2

CSPI Center for Science in the Public Interest

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